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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,964	10/22/2001	Shin Nakamura	011361	8556

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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT PAPER NUMBER

1753

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/982,964

Applicant(s)

NAKAMURA ET AL.

Examiner

Jeffrey T Barton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Non-US Patent Literature.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references (Anal. Chem. references) in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

2. Figures 14B and 14C should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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***Specification***

3. The abstract of the disclosure is objected to because of grammatical errors and awkward construction that render it unclear. Correction is required. See MPEP § 608.01(b).

4. Claims 1-3 and 10 are objected to because of the following minor informalities:

Claims 1, 3, and 10: Subject/verb agreement – “. . . that is formed . . .” should be revised to “. . . that are formed . . .”, since the holes are the subject.

Claim 2: “therein” should be replaced with “thereon”, since the electrophoretic members rest on the planar member. Also, in referring to “plurality of the electrophoretic members”, the article “a” should be replaced with “said”, because this plurality was previously described in claim 1.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language and construction of these claims render them unclear. Some suggested revisions in language and comments are given below as examples, but revision of the entire text of these claims is suggested.

In both claims, replacing the phrase, "provided as the passage," with "provided with a passage" would clarify the meaning. Replacing the entire clause with, "the passage on the electrophoretic member comprises a specimen injection passage and a separation passage, which intersect each other, and" would be clearer still.

The phrase "for once stopping the electrophoretic apparatus" is not clear. Is "at once", or "immediately" stopping the apparatus, the intended meaning?

7. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite the limitation "the reservoirs" in the fourth paragraph of claim 10, and the first paragraphs of both claims 11 and 12. There was no prior description of the reservoirs in the claims, and thus there is insufficient antecedent basis for this limitation in these claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Adourian et al.

Addressing claims 1, 2, and 10, Adourian et al disclose an electrophoretic apparatus that comprises: an electrophoretic member in which a disk shaped member thereof has a plurality of passages formed therein (Figures 10 and 11A, channels 152 and 194; Column 15, lines 14-41); holes reaching the passage formed at positions corresponding to both ends of the passage, on one surface of the disk-shaped member (Figure 11A, wells 190, 192, 194, 196; Column 15, lines 41-45; Figure 8A-C; Column 13, lines 24-32; Figure 7, openings 126 and 130); voltage applying parts for applying

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voltages across the passages of the electrophoretic member (Figure 7; Column 13, lines 14-19; Cathode and anode reservoirs in Figure 10; Column 15, lines 41-45); and a detecting part for detecting a specimen present in the passages of the electrophoretic member (Figure 11B, detector 202; Column 15, lines 56-61; Column 17, lines 22-33)

Further addressing claim 1, Adourian et al disclose an electrophoretic member holding part for holding a plurality of the electrophoretic members engaged in simultaneous electrophoretic operations. (Figure 11, platter 191, microchips 120a and 120b; Figure 1, support assembly 24; Column 12, lines 21-33; Figure 5)

Further addressing claim 2, Adourian et al disclose the electrophoretic member holding part (Figure 11, platter 191) as holding a plurality of the electrophoretic members (Figure 11, microchips 120a and 120b; Column 15, lines 28-31) on a planar member (platter 191, planar as illustrated in Figure 11) to rotate the plurality of electrophoretic members, sequentially locating one end of each of the passages at a specimen dispensing position. (Column 15, lines 51-56) Adourian et al also disclose a robotic dispensing mechanism for dispensing a specimen into the hole corresponding to one end of the passage positioned at the specimen dispensing position. (Figure 1, fluid transfer device 42; Column 8, lines 61-63; Column 15, lines 43-45 and 51-56)

Further addressing claim 10, Adourian et al disclose an electrophoretic medium filling mechanism for filling the passages and reservoirs with an electrophoretic medium, through the reservoirs of the electrophoretic member (Column 10, lines 32-39; Column 21, lines 15-27 – both methods can fill reservoirs, and it might be unavoidable given the narrowness and geometry of the channels and the lack of disclosure of means to avoid

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reservoir-filling); a specimen injection mechanism for injecting a specimen into one of the reservoirs (Column 15, lines 43-45 and 51-56); and a control part for controlling the electrophoretic apparatus, including the mechanisms, so that they all may operate automatically. (Figures 1 and 4, controllers 30 and 110)

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al in view of Smith et al.

Adourian et al disclose an apparatus as described above. In addition, they disclose a detecting part consisting of a fluorescent light-detecting device in a detecting range (Column 17, lines 22-33; Column 18, lines 27-31) (Claim 3), and a specimen injection-monitor mechanism for detecting a specimen at a site where the specimen is injected into the passage. (Column 26, lines 10-29) (Claim 5)

Adourian et al do not explicitly disclose the use of a fluorescent light-detecting device comprising: a first optical system for focusing light from a detecting range into a slit hole for image formation, and a second optical system provided with a reflection-type diffraction grating, for separating the light from the slit hole and focusing the light onto a detecting element for image formation. (Claim 3) Adourian et al also do not



explicitly disclose the use of a second optical system consisting of only a concave reflection-type diffraction grating. (Claim 4)

Smith et al disclose a capillary electrophoresis apparatus that includes a fluorescent light-detecting device that comprises: a first optical system for focusing light from a detecting range into a slit hole for image formation (Column 7, line 1 – Column 8, line 8; Figure 1A shows all components); a second optical system provided with a reflection-type diffraction grating, for separating the light from the slit hole and focusing the light onto a detecting element for image formation (Figure 1A, slit 121, grating 120; Column 8, line 1 – 8); and the second optical system consisting of only a concave reflection-type diffraction grating (grating is only component between slit and detector, see Figure 1A; Column 8, lines 9-16)

Adourian et al and Smith et al are analogous art in that both describe capillary electrophoresis systems with fluorescence detectors.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Adourian et al by replacing the optics of their detector with the optics of Smith et al, because it could improve detection sensitivity.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al and Smith et al as applied to claim 5 above, and further in view of Birnbaum et al.

Adourian et al and Smith et al disclose devices as described above.

Neither Adourian et al nor Smith et al explicitly disclose a specimen injection-monitoring system for detecting a specimen at a site where it is injected into the

passage, with this system sharing an excitation light source with the detecting mechanism, and the monitoring system and detecting mechanism each being provided with a fluorescent light-detecting optical system.

Birnbaum et al disclose a fluorescence detector for use in capillary electrophoresis that probes the whole capillary (including the injection site) by irradiating the length of the capillary with one light source, and detecting fluorescence from the sample components (see the abstract, second sentence; Figure 1).

Adourian et al, Smith et al, and Birnbaum et al are analogous art in that all describe capillary electrophoresis systems with fluorescence detectors.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combination of Adourian et al and Smith et al by configuring their detector to scan the entire capillary length, as taught by Birnbaum et al, because it would provide more separation data. Such a system would be functionally equivalent to a separate detector with independent optics monitoring the injection site.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al and Smith et al as applied to claim 5 above, and further in view of Manian et al.

Adourian et al and Smith et al disclose devices as described above.

Neither Adourian et al nor Smith et al explicitly disclose a fluorescence detection system that uses an LED light source.

Manian et al disclose a fluorescence detector for use in capillary electrophoresis that uses an LED light source (Column 4, lines 62-66)

Adourian et al, Smith et al, and Manian et al are analogous art in that all describe capillary electrophoresis systems with fluorescence detectors.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combination of Adourian et al and Smith et al by using an LED light source for the detector, as taught by Manian et al, because it would be less expensive and more rugged.

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al and Smith et al as applied to claim 5 above, and further in view of Uchigaki et al.

Adourian et al and Smith et al disclose devices as described above. Adourian et al further disclose a control part for permitting the voltage applying part to supply a voltage for guiding a specimen to an intersection between the specimen injection passage and the separation passage (See Figure 8A-C)

Neither Adourian et al nor Smith et al explicitly disclose a control part that can immediately stop the apparatus in case of nonuniform specimen distribution (Claim 8) or failure to inject a sample from the specimen injection passage to the separation passage (Claim 9)

Uchigaki et al disclose a liquid analysis device that includes means for shutting down an analysis in case a pipetting step (injection step) is not correctly carried out. (Column 12, lines 50-55) Detection of such a situation can be carried out by optical means (Column 8, line 54 – Column 9, line 2)

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Adourian et al, Smith et al, and Uchigaki et al are analogous art in that all describe liquid analysis systems with optical detectors.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combination of Adourian et al and Smith et al by creating a control program that would shut down the analysis if there was an injection irregularity detected at the injection site, as taught by Uchigaki et al, because it would increase efficiency by preventing time lost in unreliable analyses.

15. Claims 11 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al in view of Menchen et al.

Adourian et al disclose an automated apparatus as described above in the treatment of claim 10. Adourian et al further disclose a buffer-liquid injecting mechanism for injecting buffer liquid into the reservoirs and the fact that this mechanism is controlled by the control part. (Column 21, lines 15-49)

Adourian et al do not explicitly disclose an electrophoretic medium-sucking mechanism for removing electrophoretic medium contained in the reservoirs, nor do they disclose a specimen sucking mechanism for removing specimen left in the reservoirs after the specimen is injected into the passages.

Menchen et al disclose a capillary electrophoresis apparatus that includes a reservoir equipped with a vacuum system for drawing fluids from the reservoir (Figure 10, vacuum system 86, tube 84; Column 17, lines 63-66) Such a vacuum could remove either specimens or electrophoretic medium from the reservoir.

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Adourian et al and Menchen et al are analogous art in that both describe capillary electrophoresis systems.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Adourian et al by adding a vacuum mechanism for withdrawing fluids from the reservoirs, as taught by Menchen et al, because it could conserve limited sample volumes or facilitate full automation by cleaning the reservoirs of gel prior to sample injection.

In such a combination, it would also be obvious to control the vacuum mechanism by the same control part as the rest of the apparatus, for ease of operation.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Edwards et al disclose a disk-shaped electrophoretic member with a plurality of channels and similar construction and operation. (Both EP 934771A1 and US 6,132,579)

Shi et al, Andresen, and Regnier et al disclose disk-shaped electrophoretic members with a plurality of channels and automated operation.

Maracas et al disclose a similar automated electrophoresis system.

Nakanishi et al (Both JP 10132783 and US 6,042,708) and Tanaka (Both JP 2000227414 and 2000283960) disclose detectors able to probe the length of the

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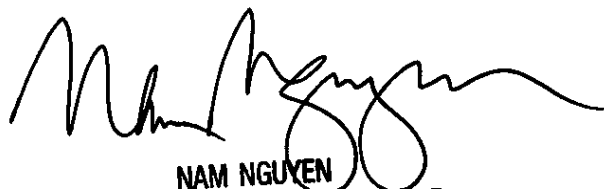
capillary, including the injection site. These devices could be construed as specimen injection-monitoring systems.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB  
June 8, 2004



NAM NGUYEN  
SUPERVISORY PATENT EXAMINER  
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reservoir-filling); a specimen injection mechanism for injecting a specimen into one of the reservoirs (Column 15, lines 43-45 and 51-56); and a control part for controlling the electrophoretic apparatus, including the mechanisms, so that they all may operate automatically. (Figures 1 and 4, controllers 30 and 110)

***Claim Rejections - 35 USC § 103***

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